UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,016	01/23/2004	David Fikstad	23625.CON	8956

20551 7590 04/20/2006

THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
SANDY, UT 84070

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,016	FIKSTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-36 are presented for examination.

Applicant's Amendment, Terminal Disclaimers and literature reference to Steel et al. filed January 17, 2006 have each been received and entered into the present application. Accordingly, the specification at pages 1, 8, 10-17, 26-27, 31-34 and 36-41 has been amended, claims 3-11 and 19 have been amended and claims 34-36 are newly added.

Applicant's Petition for acceptance of an unintentionally delayed claim for priority under 37 C.F.R. 1.78(a)(3) filed December 1, 2005 was **GRANTED** January 10, 2006. Accordingly, the specification at page 1 has been amended to reflect the updated claim for priority under 35 U.S.C. 120.

Applicant proposes an amendment to the specification at the fourth paragraph beginning on page 8. However, such a reference is in error. The cited paragraph to be amended appears at page 30 of the disclosure.

In view of the foregoing amendments, remarks and petitions, the objections to the claims; the objections to the specification; the rejection of claims 3, 7-12 and 21-23 under 35 U.S.C. 112, second paragraph; the rejection of claims 1-26 and 28-33 under 35 U.S.C. 102(a) or 102(e); and the rejection of claims 1-33 under 35 U.S.C. 103(a) as set forth at pages 2-18 of the previous Office Action dated July 13, 2005 have each been hereby **withdrawn**.

It is noted that the prior art rejections under 35 U.S.C. 102(a) or 102(e) and 35 U.S.C. 103(a) are withdrawn in light of Applicant's amended claim for priority, which renders the primary reference unavailable as prior art.

In view of the acceptable nature of the 19 Terminal Disclaimers filed January 17, 2006, the rejections of the present claims under the judicially created doctrine of obviousness-type double patenting over various copending U.S. Patent Applications and issued U.S. Patents have each been hereby **withdrawn**.

Objection to the Specification (New Ground of Objection)

Applicant's amendment to the specification adding the priority data at page 1 has been noted. However, Applicant has failed to provide the filing date of U.S. Patent Application No. 09/447,690. Applicant may wish to consider amending the priority data in the following manner. Acceptance of such a suggestion does not necessarily equate to the claims being free of the cited prior art.

---This application is a continuation of U.S. Patent App. No. 10/700,838 filed on November 3, 2003, which is a continuation in part of U.S. Patent App. No. 10/428,431 filed on May 1, 2003, now issued as U.S. Patent No. 6,923,988, which is a continuation of U.S. Patent App. No. 09/800,593 filed on March 6, 2001, now issued as U.S. Patent No. 6,569,463, which is a division of U.S. Patent App. No. 09/447,690, filed November 23, 1999, now issued as U.S. Patent No. 6,248,363.---

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15, 17-18 and 30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons set forth at pages 4-5 of the previous Office Action dated July 13, 2005, of which said reasons are herein incorporated by reference.

Applicant traverses the rejection and references MPEP §2173.05(b) in support of the position that the term "about" has been held to be definite with respect to numerical ranges such as those in the present claims.

While Applicant's reliance upon the MPEP at §2173.05(b) has been carefully considered, Applicant is reminded that each case is decided on its own merits. In view of the present set of facts, the present rejection is properly maintained because Applicant has not made clear on the record which term is meant to limit the claim. Claims 13-15 read upon the phrase "less than about", claims 17-18 read upon the phrase "more than about" and claim 30 reads upon the phrase "less than or equal to about". The presence of the word "about" denotes that the numerical range may be slightly greater or slightly less than the recited endpoints. However, the presence of limiting terms, such as "less than", "more than" or "less than or equal to" are fixed endpoints that do not generally allow for variability above or below the recited endpoint(s). For these reasons, the numerical range(s) intended to be encompassed by the present claims would be open to subjective interpretation by one of ordinary skill in the art and would not reasonably inform such an individual of the metes and bounds of the claim such that infringement of the claim(s) could be determined.

Applicant may wish to consider amending the claim in a manner consistent with the amendment made to present claim 19 to overcome the present rejection.

For these reasons, and those already made of record at pages 4-5 of the previous Office Action dated July 13, 2005, rejection of present claims 13-15, 17-18 and 30 remains proper and is **maintained**.

Claim Rejection - 35 USC § 112, Second Paragraph (New Ground of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173: "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what Applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph, with respect to the claimed invention." (See MPEP §2173).

In particular, Applicant has amended claim 8 to now read upon "a dissolving salt of a complex", but has not clearly delineated what the complex is, what kind of salts are intended and in what the complex is dissolving. The specification also fails to provide a clear, deliberate and precise definition of this "dissolving salt of a complex" such that the skilled artisan would have been reasonably apprised of the metes and bounds of the claimed subject matter for which

Applicant seeks protection. For these reasons, one of ordinary skill in the art would not be able to readily determine what would constitute infringement of the present claims.

In light of such, claims 8-12 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejection - 35 USC § 102 (New Ground of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16, 20-26 and 28-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (U.S. Patent No. 6,294,192; Issued September 2001; Filed February 26, 1999) in light of Stedman's Medical Dictionary (1972, p.595 and 1400).

In accordance with the MPEP at §2131.01, it is proper to rely upon a secondary reference for a rejection under 35 U.S.C. 102, provided that the additional reference is relied upon in order to explain the meaning of a term used in the primary reference.

Patel et al. teaches a pharmaceutical composition comprising pioglitazone (col.22, l.53), zafirlukast (col.22, l.23), simvastatin (col.24, l.29-30), atorvastatin (col.24, l.27), fenofibrate (col.24, l.28) or amiodarone (col.22, l.21), combined with surfactants such that the combination

can solubilize therapeutically effective amounts of hydrophobic therapeutic agents such that they result in an enhanced rate and/or extent of absorption of the hydrophobic therapeutic agent (col.4, l.50-62). Patel et al. teaches formulation of the therapeutic agent with a variety of surfactants and solubilizers, including:

(1) polyoxyethylene-polyoxypropylene block copolymers (col.16, l.32-33), (2) cyclodextrins and cyclodextrin derivatives (col.25, l.26-27), including hydroxypropylcyclodextrins or sulfobutyl ether derivatives of cyclodextrin (col.55, l.37-38), (3) derivatives of fat soluble vitamins, such as vitamin E or tocopherol PEG-1000 succinate or other polyethoxylated fat-soluble vitamins or derivatives (col.11, l.11-15), (4) polyglycerized fatty acids (col.11, l.16), (5) glycerol/propylene glycol fatty acid esters (col.12, l.46), (6) sorbitan fatty acid esters (col.14, l.40), (7) sorbitol (col.25, l.23), (8) polyethylene glycol fatty acid esters (col.6, l.20; col.7, l.40; col.8, l.17), (9) lactic acid derivatives of mono- or di-glycerides (col.47, l.61-63), (10) PEG-35 castor oil (col.9-10, Table 5; also known as CREMOPHOR EL, which Applicant acknowledges at page 12, line 28 is equivalent to polyoxyl 35 castor oil), (11) PEG-8 caprylic/capric glycerides (col.9-10, Table 5), (12) PEG-20 sorbitan monooleate (col.15, Table 11; also known as polysorbate 80, which Applicant acknowledges at page 14, lines 8-9), (13) sorbitan monooleate (col.17, Table 16); (14) mono- or di-glycerides and acetylated mono- or di-glycerides (col.12, l.63; col.13, Table 9), (15) PEG-6 corn oil (col.9-10, Table 5; also known as LABRAFIL M 2125 CS, which Applicant acknowledges at page 14, lines 1-2 is equivalent to linoleoyl monoglycerides), (16) lauroyl macrogol-32-glycerides (col.9-10, Table 5), (17) hydrogenated vegetable oils (col.48, l.44-45), (18) polyglyceryl-3-distearate (col.11, Table 6), (19) stearoyl macrogolglyceride (col.9-10, Table 5; also known as GELUCIRE 50/13, which

Applicant acknowledges at page 12, line 33-page 13, line 1 is equivalent to stearoyl macrogol-32-glycerides), (20) calcium/sodium stearoyl lactylate (col.19, Table 18), (21) stearic acid (col.51, l.38), (22) sucrose distearate (col.16, Table 13), (23) sucrose monopalmitate (col.16, Table 13), (24) sucrose dipalmitate (col.16, Table 13), and (25) PEG-40 hydrogenated castor oil (col.9-10, Table 5; also known as CREMOPHOR RH40, which Applicant acknowledges at page 12, line 27 is equivalent to polyoxyl 40 castor oil).

A variety of additives are taught at col.26, lines 16-23.

Patel et al. also teaches the use of polyvinylpyrrolidone (col.25, l.37-38) or hydroxypropylmethylcellulose (col.25, l.25-26) and further teaches that the composition may be formulated into an enteric coated capsule for oral administration (col.26, l.32-34), or may be formulated for topical, transdermal, ocular, pulmonary, vaginal, rectal, transmucosal or parenteral administration in the form of a cream, lotion, ointment, suppository, gel or the like (col.26, l.46-52).

With regard to present claims 21-23, directed towards the synchronized release of the drug and solubilizer with particular correlation coefficients of grater than 0.80 (see present claim 21), greater than 0.90 (see present claim 22) and greater than 0.95 (see present claim 23), such correlation values are, absent factual evidence to the contrary, present in the reference because Patel et al. teaches the formulation of the same materials as presently claimed to produce the same composition. Thus, absent any patentable difference between the composition of the reference and that of the present claims, any release properties of the composition are necessarily present in the composition of the prior art.

Patel et al. teaches the use of lactic acid derivatives at col.47, lines 61-63, where lactic acid is known in the art to be synonymous with a hydroxy-acid as recited in present claim 6 (see Stedman's Medical Dictionary, 1972, p.595) and, thus, anticipates this claim limitation. Furthermore, Patel et al. teaches the use of Vitamin E in the disclosed pharmaceutical composition, which is known in the art to be synonymous with alpha-tocopherol (see Stedman's Medical Dictionary, 1972, p. 1400) and, thus, anticipates the claim limitation of alpha-tocopherol in present claims 5 and 11.

While the limitation of "wherein the aqueous solubility of the drug is dependent on pH" in present claim 29, such is not considered to further limit the composition of parent claim 1 because such a limitation does not impart any physical or material property to the composition that is not already present in the claim from which it depends.

In addition, because Patel et al. teaches the same therapeutic agent(s) as presently claimed, the aqueous solubility or pKa values as recited in the present claims (see present claims 13-15) do not differ from those of the active agents taught by the reference, absent factual evidence to the contrary.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejection - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Patent No. 6,294,192; Issued September 2001; Filed February 26, 1999) in light of Stedman's Medical Dictionary (1972, p.595 and 1400), in view of Lambert et al. (U.S. Patent No. 6,458,373; 2002) and The Merck Index (Monograph 1882; 1989), Patel et al. (U.S. Patent No. 6,309,663; 2001), Chen et al. (U.S. Patent No. 6,623,755; 2003) and Royce (U.S. Patent No. 5,403,593; 1995).

Please reference above under "Claim Rejection-35 U.S.C. 102" for the teachings of Patel et al. (U.S. Patent No. 6,294,192; Issued Sept. 2001; Filed Feb. 1999).

The differences between the Patel et al. reference and the presently claimed subject matter lie in that the reference fails to teach:

(i) the use of tocols such as alpha-tocopherol ester, alpha-tocopherol acetate, alpha-tocopherol nicotinate, alpha-tocopherol succinate, alpha-tocopherol polyethylene glycol succinate of various molecular weights (400 or 200-8000) and d- or dl-alpha-tocopherol polyethylene glycol 1000 succinate;

(ii) the use of carvedilol, dronederone, risperidone or ziprasidone; or

(iii) the use of a release modulating osmotic pump, erodible matrix, ion-exchange resin, waxes, such as microcrystalline wax, yellow wax, white wax, nonionic emulsifying wax or cetyl esters wax, glycerol palmitostearate, glycerol dipalmitate, or polymeric coating, such as an acrylic polymer, shellac or polyvinyl acetyl phthalate or release over more than 1 or 2 hours or between 2 and 24 hours.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Lambert et al. (U.S. Patent No. 6,458,373; 2002) provides teachings of various well known derivatives of vitamin E, such as alpha-tocopherol esters, including alpha-tocopherol acetate, alpha-tocopherol succinate, alpha-tocopherol nicotinate and tocopherol polyethylene glycol succinate (also known as d-alpha-tocopherol polyethylene glycol 1000 succinate; see col.5, lines 10-14 and col.22, lines 54-57) used in the formulation of poorly water-soluble drugs. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the

invention to employ any one or more of these known vitamin E derivative compounds in the composition disclosed by Patel et al. Such a person would have been motivated to do so because Patel et al., in its broadest embodiment, teaches the use of vitamin E or its derivatives and it would have been reasonably expected that the use of any one or more of the vitamin E derivatives known and taught by Lambert et al. would have retained the same, or substantially similar, efficacy to that of vitamin E itself and, thus, would not have been expected to significantly alter the function or activity of the composition. In fact, it would have been reasonably expected that the presence of such vitamin E derivatives would assist the solubilization of the poorly water-soluble therapeutic agent.

The use of various molecular weight or enantiomeric forms (e.g., dl-alpha-tocopherol polyethylene glycol 1000 succinate) of the vitamin E component would have been a matter well within the purview of the skilled artisan because the components would have been reasonable expected to function in a manner consistent with that of other known vitamin E components with varying molecular weight or enantiomeric form, absent factual evidence to the contrary. Therefore, the use of such vitamin E components in the composition disclosed by Patel et al. would have been expected to retain the same level of efficacy as other vitamin E derivatives of other molecular weights or enantiomeric form and the use of such forms would not have been expected to materially alter the activity of the composition.

(ii) Patel et al. teaches the use of antiarrhythmic agents, antihypertensive agents or anxiolytic agents as the active therapeutic agent of the disclosed pharmaceutical composition. The broad teaching of antiarrhythmics, antihypertensives or anxiolytics as general classes of agents would have placed the use of compounds such as carvedilol (an antihypertensive, see

Monograph 1882 at page 286 of The Merck Index), dronederone (an antiarrhythmic) or risperidone or ziprasidone (both antipsychotics) well within the purview of the skilled artisan. Such a person would have been motivated to use any one or more of these agents in the disclosed composition of Patel et al. in order to enhance the therapeutic effect and bioabsorption and to sustain such an effect for a longer period of time. In particular, the skilled artisan would have appreciated that better bioabsorption and prolonged therapeutic effect would reduce the frequency of administration of such agents, which, for a chronic condition, such as hypertension, would further enhance patient compliance with the regimen.

(iii) The determination of the optimum formulation of the disclosed pharmaceutical composition of Patel et al. would have also been a matter well within the purview of the skilled artisan. The use of dosage formulations that exert immediate release, controlled release, extended release, delayed release and targeted delayed release were formulations well known in the art at the time of the invention. Alteration of the release characteristics into any one or more of these dosage formulations requires specific components to effect a particular release profile. Patel et al. (U.S. Patent No. 6,309,663; Issued October 2001; Filed August 17, 1999) teaches a variety of release modulating components, such as polymeric matrices, coated matrices, ion-exchange resins, osmosis based composition or biodegradable polymers, such as shellac, cellulose derivatives, such a hydroxypropylmethylcellulose, or other polymers such as polyvinyl acetate phthalate (col.38, lines 6-17 and col.39, line 37-col.40, line 30), commonly incorporated in various pharmaceutical formulations to alter the release of the active agents.

Various wax coatings, such as microcrystalline wax, yellow wax, white wax, nonionic emulsifying wax or cetyl esters wax, were also commonly used in the formulation of

pharmaceuticals (see Chen et al., col.6, lines 45-60 and col.7, lines 3-4) such that the metabolism of such formulations would have necessarily been affected by the thickness and permeability of such a wax coating. Surfactants such as glycerol palmitostearate or glycerol dipalmitate were also commonly used in the formulation of pharmaceutical preparations (see abstract and col.4, lines 32-50 of Royce) and would have been expected to alter the solubility and, thus, the bioavailability and bioabsorption of the therapeutic agent to be administered.

Use of any one or more of such release modifying agents would have been *prima facie* obvious to one of ordinary skill in the art motivated to optimize a pharmaceutical dosage form to achieve the maximum or most beneficial therapeutic effect possible. Such modulating agents were each well known in the art and would have naturally commended themselves to one of ordinary skill in the art at the time of the invention. Furthermore, the determination of the optimum period of time over which release of the therapeutic agent would occur would have been a matter well within the purview of one of ordinary skill in the art and would have been made in accordance with the therapeutic effect desired, toxicological and pharmacologic considerations and patient compliance with the therapeutic regimen.

Double Patenting

Applicant's attention is directed to the MPEP at §2001.06(b)[R-2]:

"The individuals covered by 37 C.F.R. 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are "material to patentability" of the application in question." See *Armour & Co. v. Swift & Co.*,

466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972).

Insofar as Applicant failed to bring the present copending U.S. Patent Application No. 11/122,788 to the Examiner's attention, and further insofar as the claims of this same copending application were not available to the Examiner for review at the time of the previous Office Action because the application was still in the pre-examination, the present rejection is proper and is set forth below.

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-2 and 16-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 and 17-34 of copending U.S. Patent Application No. 11/122,788. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending U.S. Patent Application No. 11/122,788.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '788 application are not considered to be patentably distinct from each other because the present claims clearly anticipate the copending claims. The present claims clearly provide for a pharmaceutical composition and solid oral dosage forms thereof, containing a therapeutically effective amount of a drug, a solubilizer and a release modulator, wherein the release of the drug and the solubilizer are synchronized, and further wherein the same active agents, solubilizers and release modulators provided for in the present claims are the same as those used in the copending claims. For these reasons, the present claims and those of the '788 application are not patentably distinct from one another.

Accordingly, rejection of present claims 1-36 is deemed proper over claims 1-34 of U.S. Patent Application No. 11/122,788 as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 1-36 is deemed proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 14, 2006

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600